400-DS Apparatus 7

Operator's Manual

Agilent Technologies

Notices

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Manual Part Number

70-9064

Edition

Rev A, August 2011

Printed in USA

Agilent Technologies, Inc.
3501 Stevens Creek Blvd.
Santa Clara, CA 95052 USA

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Safety Notices

CAUTION

A **CAUTION** notice denotes a hazard. It calls attention to an operating procedure, practice, or the like that, if not correctly performed or adhered to, could result in damage to the product or loss of important data. Do not proceed beyond a **CAUTION** notice until the indicated conditions are fully understood and met.

WARNING

A WARNING notice denotes a hazard. It calls attention to an operating procedure, practice, or the like that, if not correctly performed or adhered to, could result in personal injury or death. Do not proceed beyond a WARNING notice until the indicated conditions are fully understood and met.

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1 Safety

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The 400-DS has been carefully designed so that when used properly you have an accurate, fast, flexible, and safe instrument.

If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

Operation of an Agilent 400-DS involves the use of aqueous liquids and various pharmaceutical dosage forms. Unskilled, improper, or careless use of this instrument can create shock hazards, fire hazards, or other hazards which can cause death, serious injury to personnel, or severe damage to equipment and property.

Information on safety practices is provided with your instrument and operation manuals. Before using your instrument or accessories, you must thoroughly read these safety practices.

Observe all relevant safety practices at all times.

Electrical Hazards

The 400-DS contains electrical circuits, devices, and components operating at dangerous voltages. Contact with these circuits, devices, and components can cause death, serious injury, or painful electric shock.

Panels or covers that are retained by fasteners which require the use of a tool for removal may be opened only by Agilent-trained, Agilent-qualified, or Agilent-authorized service engineers. Consult the manuals or product labels supplied with the 400-DS to determine which parts are operator-accessible.

Application of the wrong supply voltage, connection of the instrument to an incorrectly wired supply outlet, or lack of proper electrical grounding can create a fire hazard or a potentially serious shock hazard and could seriously damage the instrument and any attached ancillary equipment.

Always use a three-wire outlet with ground connection which is adequately rated for the load. The installation must comply with local, state, and federal safety regulations.

Do not connect the instrument to the main power supply until you have made sure that the operating voltage is correctly set for the main power supply in the specific outlet in your laboratory to which the equipment will be connected.

Warning

WARNING

A ‘Warning’ message appears in the manual when failure to observe instructions or precautions could result in death or injury.

Read all warnings and cautions carefully and observe them at all times.

Caution

CAUTION

A ‘Caution’ message appears in the manual when failure to observe instructions could result in damage to equipment (Agilent supplied and / or other associated equipment).

Note

NOTE

A ‘Note’ appears in the manual to give advice or information.

Information Symbols

I	Switches main power on
0	Switches main power off
	Indicates single-phase alternating current
	Indicates the product complies with the requirements of one or more European Union (EU) directives
	Indicates specific equipment meets consensus-based standards of safety to provide assurance, required by OSHA, that these products are safe for use in the workplace for North America
	Indicates that this product must not be disposed of as unsorted municipal waste

General

CE Compliant Products

The 400-DS has been designed to comply with the requirements of the Electro-magnetic Compatibility (EMC) Directive and the Low Voltage Directive (LVD) of the EU.

Agilent, Inc. has confirmed that each product complies with the relevant directives by testing a prototype against the prescribed European Norm (EN) standards.

Proof that a product complies with the directives is indicated by:

- the CE marking appearing on the rear of the product.
- the documentation package that accompanies the product containing a copy of the declaration of conformity. This declaration is the legal declaration by Agilent, Inc. that the product complies with the directives and also shows the EN standards to which the product was tested to demonstrate compliance. The declaration of conformity is signed by the representative of the manufacturing plant.

cTUVus - U.S. and Canadian Product Approvals

The 400-DS has been designed to comply with North American safety requirements.

This product has been tested and certified for the North American market by TUV Rheinland of North America, Inc. The TUVus mark signifies that this product has been tested to U.S. standards and certified for the U.S. market. The cTUV mark signifies that this product has been tested to Canadian standards and certified for the Canadian market. When the two marks are coupled, the cTUVus mark signifies that this product has been tested to standards and certified for both markets.

WEEE Directive

All Agilent products that are subject to the WEEE directive shipped after August 13, 2005 are compliant with the WEEE marking requirements. Such products are marked with the “crossed out wheelie bin” WEEE symbol shown on page 14 in accordance with European Standard EN 50419.

This symbol on the product or on its packaging indicates that this product must not be disposed of as unsorted municipal waste. The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment.

For more information on collection, reuse, and recycling systems, please contact your local/regional waste administration, your local distributor, or Agilent, Inc.

2
Introduction

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The Agilent 400-DS Dissolution Apparatus is the first compendial small-volume dissolution apparatus for testing medical devices such as drug-eluting stents (DES). This integrated, small-footprint dissolution apparatus features several first-in-class innovations that greatly increase the convenience of release rate testing of combinatorial drug products. The 400-DS is ideal for dissolution testing of extended release products that either contain and / or release small amounts of API over time.

All parameters are controlled using the 400-DS Dissolution Workstation software via the PC. Up to 4 units can be fully programmed to execute all dissolution method and sampling parameters from a single PC. Samples can be collected in pre-capped HPLC vials for direct transfer to an HPLC system. Septa are pierced using an innovative needle manifold, which lowers and raises at each sample point. Sample trays are available in 1.5 mL and 4 mL sizes.

Conventions Used in this Manual

- Items you are asked to press are in bold. For example, “press **H** on the keypad”.

3
Setting Up the 400-DS

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Initial Setup

Complete the following sections to initially set up the Agilent 400-DS and all other system components.

Unpacking Procedure

The Agilent 400-DS is shipped in one crate. The crate contains the apparatus and accessories.

1. Open the crate and check the contents for damage, which may have occurred during shipping. Shipping damage rarely occurs, but if it does contact both the carrier who delivered the instruments and the Dissolution Systems Service Department. Though claims for damage should be filed with the carrier, we can help you file a claim.
2. Remove the top of the crate.
3. Remove one side of the crate and lift the accessories box out of the crate.
4. Disassemble the other three sides of the crate.
5. Remove any cushioning material and tape. If any item is missing, contact the Dissolution Systems Service Department or your local representative for replacements.
6. Carefully remove the apparatus from the base of the shipping crate.

WARNING **Because of its heavy weight, two people should lift the apparatus. Lift by holding underneath the base of the unit on each side. Support feet are located at each corner of the unit. Hands should be positioned between the support feet to ensure they are not trapped when lowering.**

7 Place the apparatus on a clean, dry, and level section of the bench.

NOTE The electrical connection at the back of the apparatus is the primary disconnect for the instrument. The apparatus should be positioned to allow accessibility to the power cords and circuit breaker switch for easy disconnection.

Clearance

1 Prepare the area where the equipment is to be located.

2 Ensure a minimum clearance of 40 cm above the unit and 10 cm at the rear and on both sides of the Agilent 400-DS. Approximately 65 cm x 65 cm total bench space is required per apparatus.

NOTE Ensure space is also available for the PC, media containers, and waste.

3 Orient the Agilent 400-DS and all other system components appropriately.

Parts and Accessories

Locate the following items, as applicable for your system configuration:

Item	Quantity
Agilent 400-DS Automated Apparatus 7	1
AC power cord	1
DB-9 cable	1
6-pin Mini-DIN cable	1
Sample cells	13
Cell heater jackets	13
Sample holders	13

Sample holder extraction tool	1
Roll of tubing (25 feet)	1
Sample tray with 12 rows	1
Additional sample tray for calibration	1
Magnetic plate	1
Evaporation cover with 2 guide rod stabilizer plates	1
2.5 mm Allen wrench located on rear of 400-DS	1
9/64” Allen key screwdriver	1
1.5 mm Allen key screwdriver	1
Modified temperature probe (calibration certificate included)	1
Sample vials, 12 x 32, Qty. 100	2
Sample vials, 15 x 35, Qty. 100	1
Level	1
400-DS Workstation software	1
License dongle	1
Technical Documentation CD	1

Leveling Your Apparatus

1. Place the level provided in the accessory kit on the vessel table.
2. Check the level of the instrument in the front and rear center of the unit as well as the left and right sides.
3. The apparatus has adjustable feet under each corner. These may be screwed in or out to raise or lower each leg. Adjust the feet so the bubble inside the level is within the circle at all four points.

Electrical Connection

NOTE The electrical connection at the back of the apparatus is the primary disconnect for the instrument. The apparatus should be positioned to allow accessibility to the power cords and circuit breaker switch for easy disconnection.

1 Verify the Agilent 400-DS power switch is in the off position.

2 Connect the power cord between the receptacle on the drive unit rear panel and an outlet of the appropriate voltage.

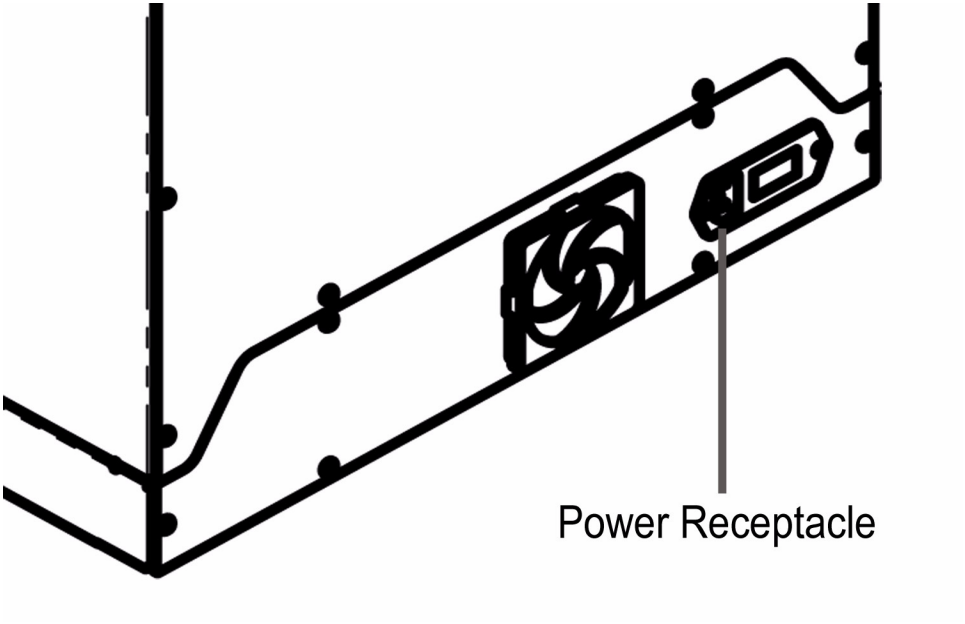


Figure 1 Diagram of the electrical connection

Consult your monitor and printer manuals for details of their individual cabling requirements.

Cable Connections

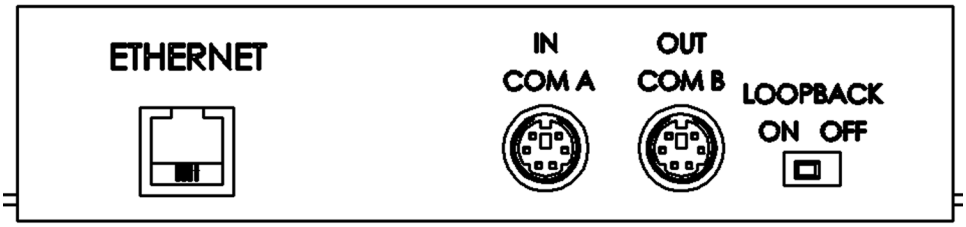


Figure 2 Diagram of cable connections

Single System Setup

1. Connect a cable between COM1 on the PC and the left serial port (IN COM A) on the rear of the Agilent 400-DS Automated Apparatus 7.
2. Ensure the loop back switch (located to the right of the right serial port) is switched to the left (ON).

Multiple System Setup

1. Connect a cable between COM1 on the PC and the left serial port (IN COM A) on the rear of the Agilent 400-DS Automated Apparatus 7.
2. Ensure the loop back switch (located to the right of the right serial port) is switched to the right (OFF).
3. Connect a 6-pin mini-DIN cable between the right serial port (OUT COM B) of the first apparatus and the left serial port of the second apparatus.
4. If this is the final Agilent 400-DS Automated Apparatus 7 in the series, ensure the loop back switch (located to the right of the right serial port) is switched to the left (ON).

If this is not the final Agilent 400-DS Automated Apparatus 7 in the series, ensure the loop back switch (located to the right of the right serial port) is switched to the right (OFF).

5. Repeat steps 3 and 4 for each additional apparatus.

Heater Jacket / Sample Holder Installation

1. Locate the 1.5 mm Allen wrench to install the sample heater jackets.
2. Install the first cell heater by placing it over the thermistor at the desired cell position of the Agilent 400-DS.
3. While holding the jacket in place, use the Allen wrench to tighten the screw. Do not overtighten the screw.
4. Insert the 2-pin plug for the heater in the appropriate location on the sample heater jacket.
5. Repeat steps 2 - 4 to install the sample heater jackets for the remaining cell positions.
6. Install the magnetic plate on the reciprocation guide rod, which is the shorter rod in the middle of the 3 rods on the Agilent 400-DS.
7. Tighten the bolt on each end of the magnetic plate using the 9/64" Allen wrench.
8. Remove the guide rod stabilizers from the bottom of the evaporation cover.
9. Install the guide rod stabilizers on top of the magnetic plate using the two longer guide rods for alignment.
10. Tighten the two bolts on each stabilizer plate using the 9/64" Allen wrench.
11. Locate the sample cells and sample holders provided with your instrument.
12. Remove the sample cells and holders from the packing material to ensure no damage occurred during shipment.
13. To install a sample cell in the heater jacket, slide one end through the magnetic lift plate. Use the finger tabs on the heater jacket to spread it open.
14. Continue to lower the sample cell until it is secure and completely covers the bottom cell seal.

CAUTION Be careful when sliding the sample cells over the O-ring seals as damage can occur. Ensure the cell and seal are properly aligned before applying pressure.

15 With the magnet at the top, insert the sample holder into the sample cell.

16 Repeat steps 13 - 15 to install the remaining sample cells and holders.

17 Replace the evaporation cover and tighten the two thumb screws.

Tubing Connections

1 If necessary, install the tubing connectors at each location of the sample valve, rinse, and waste lines.

2 Connect an adequate length of tubing to each location of the sample valve, rinse, and waste lines.

3 Place each media / rinse / waste line into an appropriate media / rinse / waste container.

CAUTION If one of the provided media bottle caps is used as a waste container, remove the dip tubes before attaching the waste line. If an alternative waste container is used, ensure that the waste connection is not capable of siphoning back into the instrument. The inlet tubing must never fall below the level of waste in the container.

The media bottles should be located at the same bench level as the 400-DS.

PC Setup

The 400-DS Workstation software requires Microsoft Windows XP®, or Windows® 7 to be installed on the computer. For instructions on installing the operating system, refer to the documentation supplied with Windows.

Minimum PC Configuration	
Windows XP or Windows 7	256 MB RAM 1024 x 768 pixel display resolution
10 GB free hard disk drive space	1x USB port

If the PC is not equipped with a standard serial port, a USB-to-serial converter must be purchased. Refer to the manufacturer's documentation for installation instructions.

If Agilent is installing the 400-DS Workstation software for you, note that the installation of a Windows® operating system is not included as part of the standard instrument installation. The monitor, keyboard, mouse, and printer/plotter are connected to the PC via cables which plug into the back of the PC.

Initial Power Up

1. Ensure the circuit breaker on the rear of the instrument is on.
2. Turn on the power switch on the front panel and ensure the integrated red LED illuminates.
3. Repeat steps 1 and 2 for each Agilent 400-DS Automated Apparatus 7.
4. Turn on the PC, monitor, and printer. Verify the PC power light illuminates and the operating system initializes.

Software Installation and Setup

NOTE To complete the installation of the 400-DS Workstation software, you must log on to the PC as an administrator. Attaching the Database and Local Security Policy are included as part of the software installation procedures. The CD contains all of the requirements for an installation.

400-DS Workstation Software Installation

1 Install the 400-DS Workstation CD and access the files.

2 Execute the file **setup.exe** and follow the on-screen prompts.

NOTE If installing the software on a Windows 7 PC, right-click **setup.exe** and select **Run as administrator**.

3 When asked if you want to install the Microsoft .Net Framework V1.1, you *must* click **Yes**.

4 After the installation has successfully completed, install the license dongle by plugging it into an open USB port. The dongle LED illuminates indicating proper driver installation.

Figure 3 License dongle

Attaching the Database

Once the basic installation is complete, complete the following steps to attach the database files:

1 Click **Start** > **All Programs** > **Agilent** > **Dissolution** > **MSDE Manager**. The MSDE Manager screen displays.

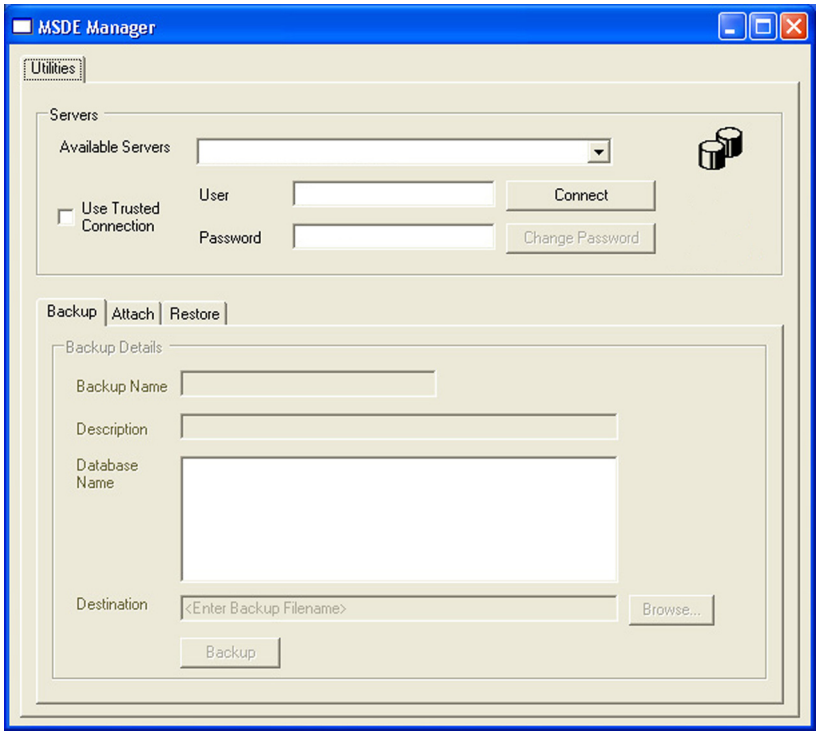


Figure 4 MSDE Manager screen

2 Select a machine name from the list of available servers. When connecting to a database installation on a local machine, the encrypted password is automatically entered in the password box. When connecting to a remote database, your system administrator may have to provide you with a password.

3 Click **Connect** to connect to the server or local PC.

4 Select the **Attach** tab on the MSDE Manager screen and attach the database by clicking **Attach**. Leave all the values at their default settings. After successful attachment, the Database Attach screen displays.

5 Click **OK**.

6 Close the MSDE Manager screen.

Local Security Policy

For 21 CFR Part 11 compliance purposes, you *must* ensure that the following minimum requirements are met by your system's security policy.

NOTE It may be necessary to coordinate the following configurations with the domain administrator.

1 Click **Start** > **Run** to run the Local Security Settings Manager. Type **secpol.msc** and press **Enter**. The Local Security Settings manager displays.

2 Click **Security Settings** > **Account Policies** > **Password Policy** and set the following security policy configuration:

Policy	Security Setting
Enforce Password History	**3 passwords remembered**
Maximum password age	**30 days**
Minimum password length	**6 characters**
Password Must Meet Complexity Requirements	**Enabled**

3 Click **Security Settings** > **Account Policies** > **Account Lockout Policy** and set the following configuration:

Policy	Security Setting
Account lockout duration	**0 minutes (infinite)**
Account lockout threshold	**3 invalid login attempts**
Reset account lockout counter	**99999 minutes**

4 Click **Security Settings** > **Local Policies** > **Audit Policy** and set the following configuration:

Policy	Security Setting
Audit account logon events	**Success, Failure**
Audit account management	**Success, Failure**
Audit logon events	**Success, Failure**
Audit policy change	**Success, Failure**

5 Close the Local Security Settings Management screen.

E-mail Notification Configuration (Optional)

1 On the computer which is hosting the DissoService, click **Start** > **All Programs** > **Agilent** > **Dissolution** > **Service Manager**. The DissoService Manager screen displays.

2 On the toolbar, click **Tools** and select **Stop Service**. The Options item on the Tools menu enables after the service stops (see Figure 5, “DissoService tools menu,” on page 33).

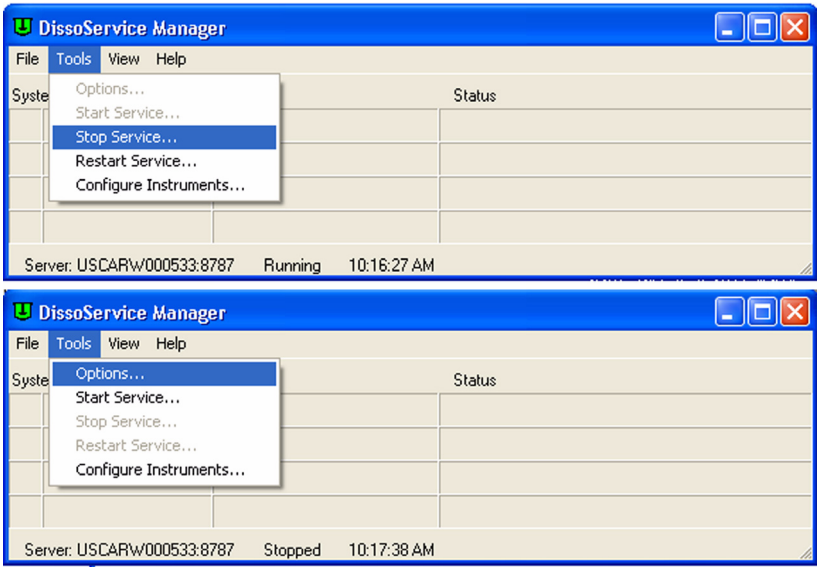


Figure 5 DissoService tools menu

3 On the toolbar, click **Tools** > **Options**. The DissoService Options screen displays (see Figure 6, “DissoService Options screen,” on page 34).

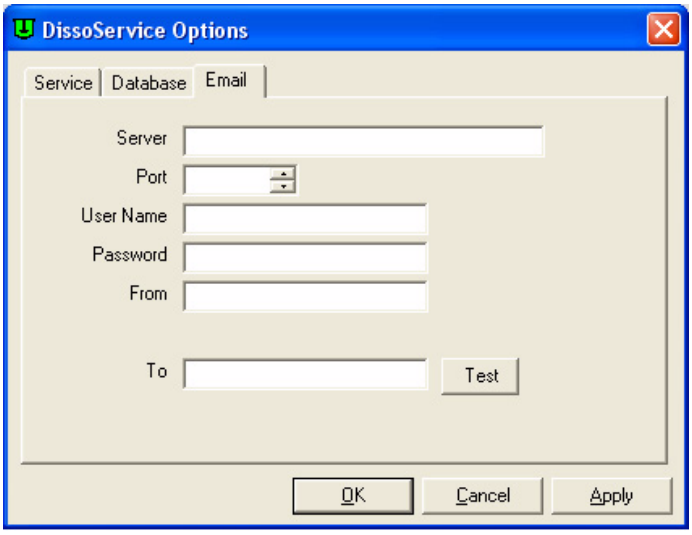


Figure 6 DissoService Options screen

4 Configure the SMTP server address.

NOTE

The e-mail alert software assumes the use of an SMTP server which does not require authentication for sending. Most e-mail servers only require authentication for receiving (POP3), but allow sending from any system on the same domain without the use of a password.

If your corporate server does not require passwords, provide the address of the corporate SMTP server in order for Dissolution Server to send e-mail. Enter the SMTP server address as either a name (for example, server.domain.com) or as an IP address (for example, 192.168.1.1).

If your corporate SMTP server requires passwords, consider installing Microsoft Internet Information Server (IIS) to a server on your intranet through which other Dissolution Servers could send e-mails. IIS includes a SMTP server which allows unrestricted e-mail sending.

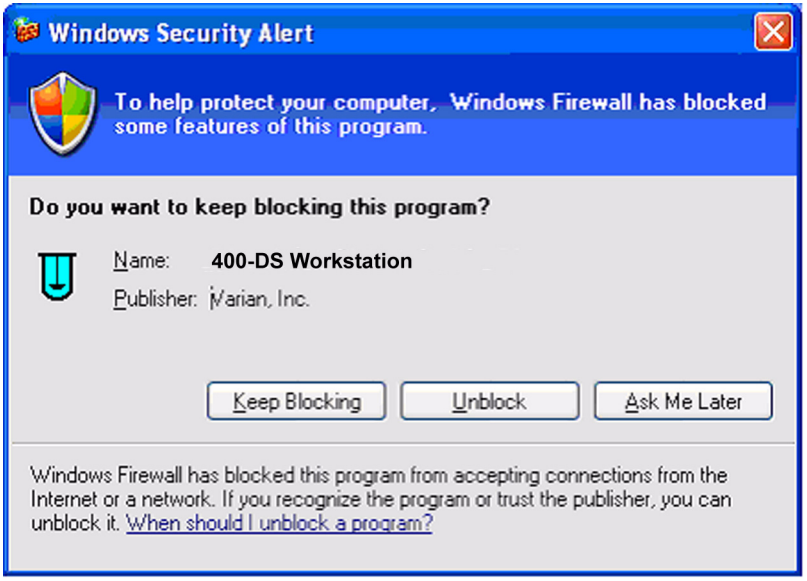
5 Once you have configured the SMTP server address, click **OK** to save the settings.

6 On the toolbar, click **Tools** and select **Start Service**.

Starting 400-DS Workstation

1 Double-click the **400-DS Workstation** icon on the Windows desktop to start the software.

2 If your system has Windows Firewall installed, the following displays:


Windows Security Alert
To help protect your computer, Windows Firewall has blocked some features of this program.
Do you want to keep blocking this program?
Name: 400-DS Workstation
Publisher: Varian, Inc.
Keep Blocking
Unblock
Ask Me Later
Windows Firewall has blocked this program from accepting connections from the Internet or a network. If you recognize the program or trust the publisher, you can unblock it. When should I unblock a program?

3 Click **Unblock** to enable the program.

Dissolution Server Selection

NOTE A dissolution server must be selected when logging into a server for the first time. The same user ID and password that was used to log on to Windows should be used to log on to the 400-DS Workstation software.

1. From the logon screen, enter a domain user identification and password.
2. Click the drop-down arrow corresponding to Dissolution server and select **Add New**. The Add New Dissolution Server screen displays

(see Figure 8, “Add New Dissolution Server screen,” on page 37).

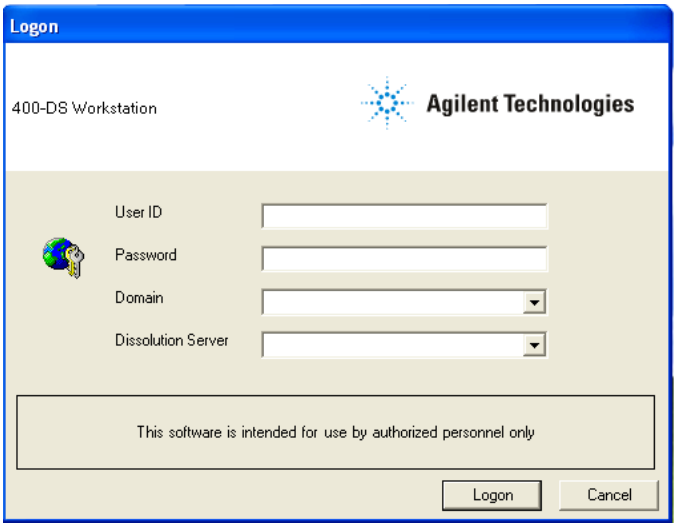


Figure 7 Logon screen

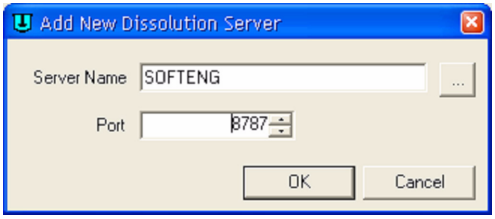


Figure 8 Add New Dissolution Server screen

3 If you know the domain name of the computer on which the Dissolution Server is installed, enter the name in the Server Name box.

Alternately, click the network browse button (…) to select a server from a list of computers on your network (see Figure 9, “Browse Dissolution Servers screen,” below).

NOTE If your network has a large number of systems connected, browsing the network may take several minutes.

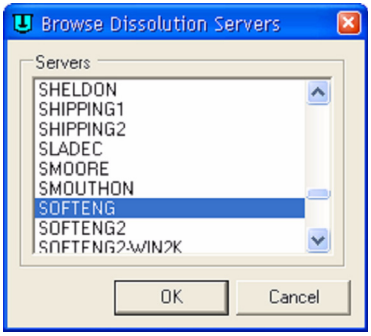


Figure 9 Browse Dissolution Servers screen

4 The default server port is 8787, but may be changed to any other port. Coordinate the selection of a port number with your I.T. department to satisfy any port restriction requirements they may have.

5 Click **OK**.

6 Click **Logon** on the Logon screen.

7 After successfully logging onto the software, click **Tools** > **Options**. The Configuration Dialog screen displays (see Figure 10, “Configuration Dialog screen,” on page 39).

Configuring the Application - Adding Users

NOTE In order to configure the application, it is necessary to be logged on as an administrator.

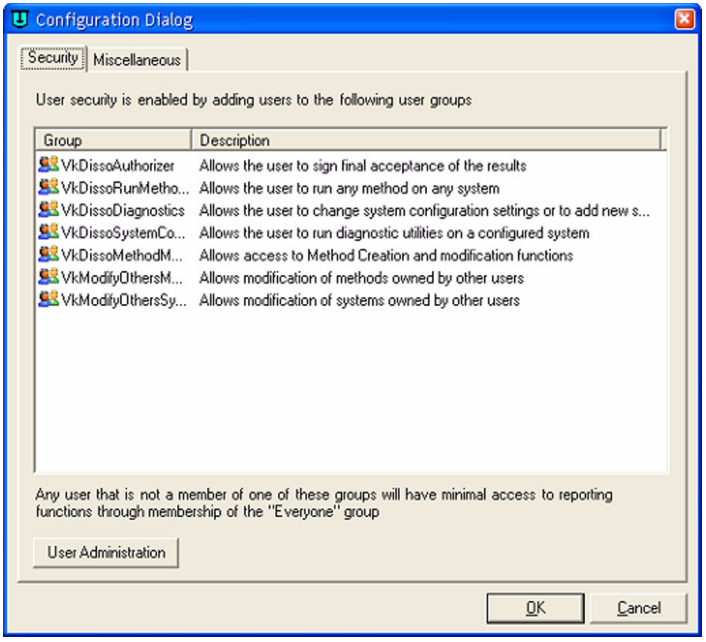

Configuration Dialog
Security
Miscellaneous
User security is enabled by adding users to the following user groups
Group
Description
VkDissoAuthorizer
Allows the user to sign final acceptance of the results
VkDissoRunMetho...
Allows the user to run any method on any system
VkDissoDiagnostics
Allows the user to change system configuration settings or to add new s...
VkDissoSystemCo...
Allows the user to run diagnostic utilities on a configured system
VkDissoMethodM...
Allows access to Method Creation and modification functions
VkModifyOthersM...
Allows modification of methods owned by other users
VkModifyOthersSy...
Allows modification of systems owned by other users
Any user that is not a member of one of these groups will have minimal access to reporting functions through membership of the "Everyone" group
User Administration
OK
Cancel

Figure 10 Configuration Dialog screen

1 To add a user to a group, select the Security tab on the Configuration Dialog screen.

2 Click **User Administration** at the bottom of the screen. The Local Users and Groups screen displays.

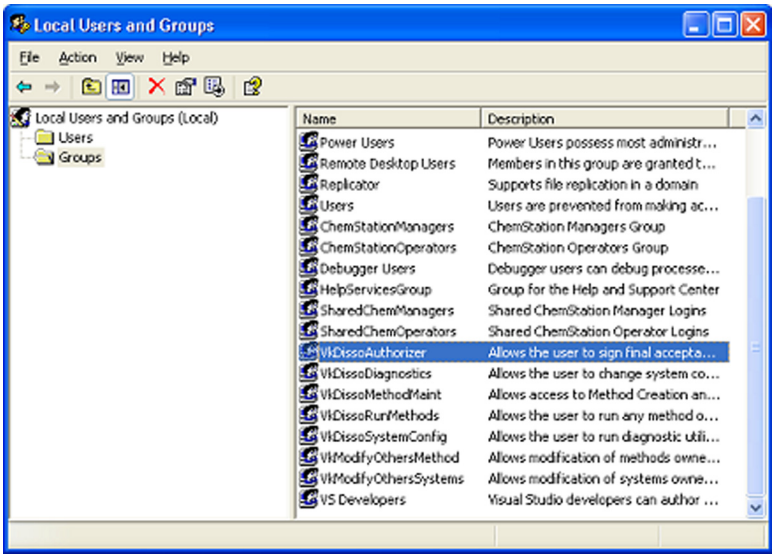


Figure 11 Local Users and Groups screen

3 Double-click the **Groups** folder to expand the list of groups.

4 Click **Add...** to add users to the group. The Select Users, Computers, or Groups screen displays.

5 Enter the names of the users to add to the group and click **OK**.

6 Repeat steps 3-5 as appropriate for each group that requires new users.

7 Close the window.

8 Enter an appropriate length of time in minutes the application can be idle before locking.

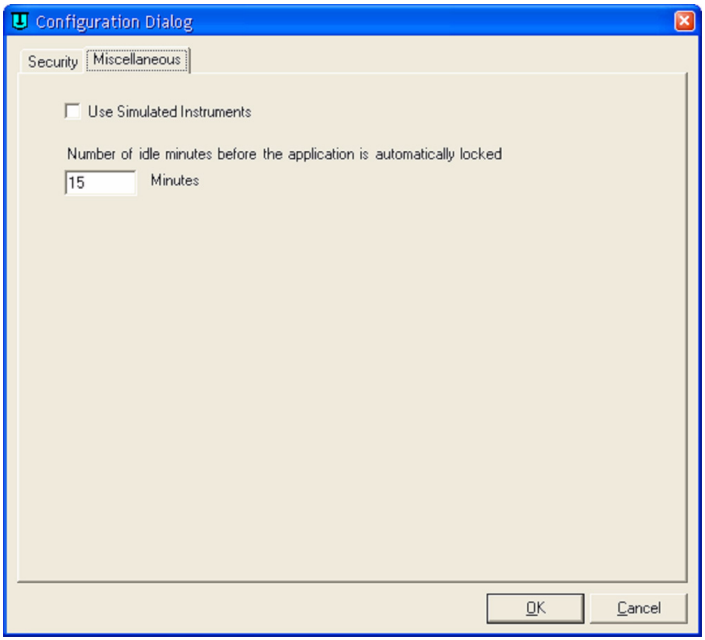


Figure 12 Miscellaneous tab

9 Click **OK**. The application has been configured.

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4
Operating the 400-DS

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400-DS Workstation Logon

1 Double-click the **Agilent 400-DS Workstation** icon on your desktop. The Logon screen displays.

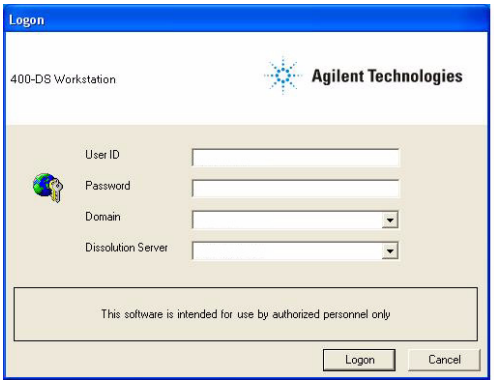


Figure 13 Logon screen

2 Enter your user identification and password. Verify the domain is correct and click **Logon**. The 400-DS Workstation screen displays.

Figure 14 400-DS Workstation Screen

NOTE Options in the left pane may be grayed out depending on user permissions.

Following is a description of the screen options listed on the navigation bar of the 400-DS Workstation screen:

Table 1 400-DS Workstation Screen Options

Option		Description
System	Configuration	Use this option to configure the system. See "System Configuration" on page 47.
	Diagnostics	Use this option to check the diagnostics of a dissolution apparatus or accessory within the system. See "Manual Control/Diagnostics" on page 62.
Method	Editor	Use this option to create a method, change or delete method parameters, run a report of the method setup, view the method audit trail, and verify the integrity of the method. See "Method Editor" on page 66.
	Run Method	Use this option to run a method. See "Running a Method" on page 80.
	Test Reports	Use this option to run a report of the completed method. See "Test Reports" on page 85.
Security	Change User	To change the user, click **Change User**. The Logon screen displays. Enter the appropriate user identification and password and click **Logon**.
	Lock Application	To lock the 400-DS Workstation screen, click **Lock Application**. The 400-DS Workstation Locked screen displays. Click the lock or the link to unlock the screen. The Logon screen displays. Enter the appropriate user identification and password as applicable and click **Logon**.
	Audit Trail	Click **Audit Trail**. The Security Audit Trail screen displays. Click **Show Report** to display the report. Change the start date, end date, and/or user identification as desired and click **Retrieve Records** to change the parameters for the information displayed.
	Permissions	Use this option to view permissions assigned to the current user and the descriptions of the corresponding privileges. Click **Permissions**. The User Group Membership screen displays.
Status		Click one of the pie-shaped graphics under status to view the status of the corresponding dissolution system.

System Configuration

It is necessary to set up the 400-DS systems that will be used. Systems can be added, modified, and removed from the database. All system configuration activity is recorded in the system audit log. The dissolution software allows the configuration of multiple systems. A maximum of four systems can be running methods at one time on a single PC.

System configuration entails selecting the appropriate equipment and setting the communication and other physical properties of the system. Serial numbers are stored for each system to allow tracking of physical system changes.

Initial Setup of 400-DS Configuration

1 From the navigation bar, click **Configuration**. The System Configuration screen displays.

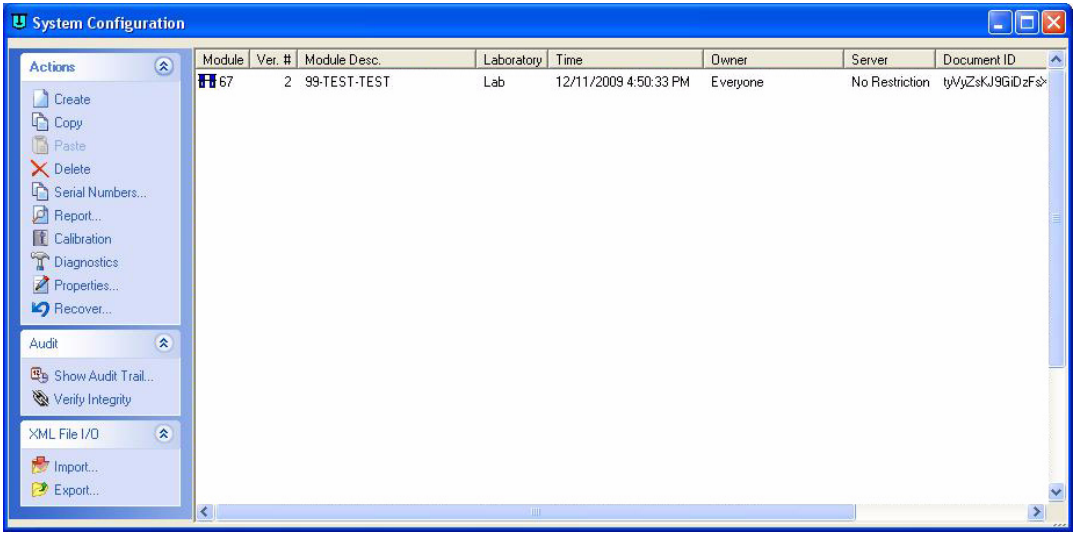


Figure 15 System Configuration screen

2 Click **Create**. The System Editor screen displays (see Figure 16, “System Editor screen,” on page 48).

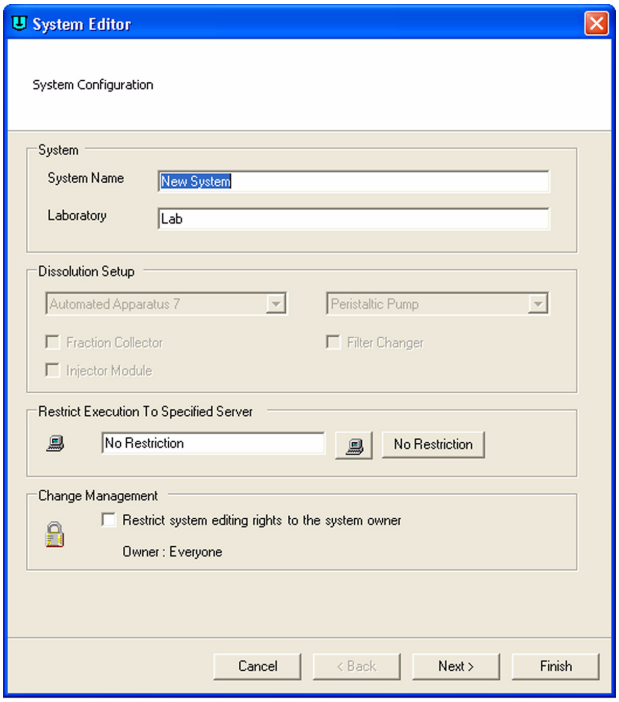


Figure 16 System Editor screen

Following is a description of the System Editor screen options:

Table 2 System Editor Screen 1 Options

Screen Section	Parameter	Description
System	System Name	Enter a name for your system.
	Laboratory	Enter a laboratory name.

Table 2 System Editor Screen 1 Options

Screen Section	Parameter	Description
Restrict Execution To Specified Server		Click to display the name of the workstation or enter the name of the workstation connected to the system. Click No Restriction to allow the system to be run from any workstation. **Note:** The system must be physically connected.
Change Management		If applicable, select the box under Change Management in order to restrict the system editing rights to the current user. **Note:** This option prevents system configuration modification by anyone other than the system owner or a user with VkModifyOthersSystems privilege.

3 Click **Next**. The next System Editor screen displays.

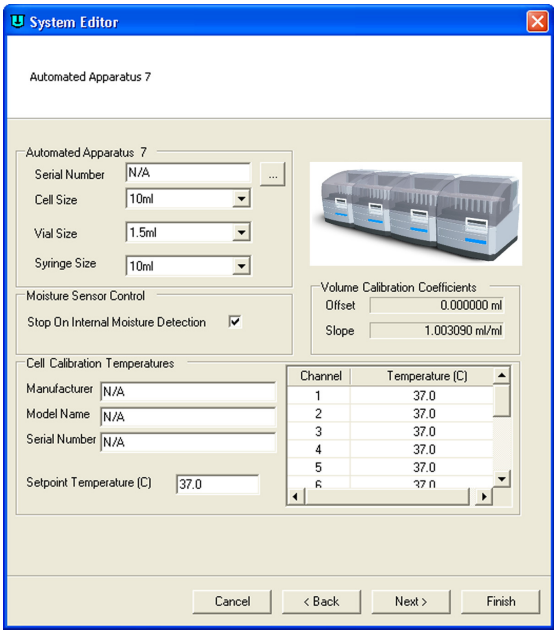


Figure 17 400-DS Workstation screen

Following is a description of the System Editor screen options:

Table 3 System Editor Screen 2 Options

Screen Section	Parameter	Response
Agilent 400-DS Automated Apparatus 7	Serial Number	Click **...** to display the serial numbers of all connected instruments. Highlight the appropriate serial number and click **Select**.
	Cell Size	Click the drop-down arrow to indicate the appropriate cell size.
	Vial Size	Click the drop-down arrow to indicate the appropriate vial size.
	Syringe Size	Click the drop-down arrow to indicate the appropriate syringe size.
Cell Calibration Temperatures	Manufacturer	Enter the manufacturer of the calibrated temperature probe.
	Model Name	Enter the model name of the calibrated temperature probe.
	Serial Number	Enter the serial number of the calibrated temperature probe.
	Set Point Temperature (ºC)	Enter the set point for the cell temperature. Enter the temperature for each cell as determined from the diagnostic (see "Temperature Calibration" on page 58).
Moisture Sensor Control	Stop On Internal Moisture Detection	Check this option to shut down the system when moisture is detected. **Note:** Enabling this option is recommended.
Volume Calibration Coefficient	Offset	The current offset displays in this area.
	Slope	The current slope displays in this area.

4 Click **Next**. The Serial Numbers screen displays.

5 Enter the serial number for the sample cells, sample holders, etc. and click **Add**.

6 Click **Finish**.

7 Repeat all the sections under "System Configuration" on page 47 for each additional system.

8 Close the System Configuration screen.

Copying a System Configuration

To copy a system configuration, complete the following steps:

1. From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 15, "System Configuration screen," on page 47).
2. Select the desired system configuration.
3. Click **Copy**.
4. Click **Paste**. A new system configuration displays. The description of the new system configuration is *Copy of...*.
5. Close the System Configuration screen.
6. To edit the system configuration, see "Editing an Existing System Configuration" on page 52.

Deleting a System Configuration

To delete a system configuration, complete the following steps:

1. From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 15, "System Configuration screen," on page 47).
2. Select the desired system configuration.
3. Click **Delete**.
4. Click **Yes**.
5. Close the System Configuration screen.

NOTE

The system configuration is never permanently deleted. It is marked as deleted in the database.

System Configuration Report

To display a report of the system configuration, complete the following steps:

1. From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 15, “System Configuration screen,” on page 47).
2. Select the desired system configuration.
3. Click **Report**. By default, the most recent report version displays.

NOTE

Alternately, you can right-click the desired system configuration and select Report. The Version Selection screen displays as a result of either of these actions.

4. Use the up and down arrows to indicate the desired report version and click **OK**.
5. The system report displays. The report can be printed, exported, searched, or verified.

NOTE

PCL6 or PPD printer drivers are required for printing a report.

Editing an Existing System Configuration

To display and edit the properties of an existing system configuration, complete the following steps:

1. From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 15, “System Configuration screen,” on page 47).
2. Select the desired system configuration.

3 Click **Properties**. The System Editor screen displays (see Figure 16, “System Editor screen,” on page 48).

NOTE

Alternately, you can double-click the desired system configuration or right-click the desired system configuration and select Properties. The System Editor screen displays as a result of any of these actions.

4 Select the appropriate tabs and change the relevant information in the same manner that the system was created.

5 Close the System Configuration screen.

Recovering a Deleted Configuration

To recover a deleted configuration, complete the following steps:

1 From the navigation bar, click **Configuration**. The System Configuration screen displays.

2 Click **Recover**. A list of the deleted systems is displayed.

3 Select the system to recover and click **OK**.

4 Verify the system is now in the current system list.

Show Audit Trail

To display the audit trail for a system configuration, complete the following steps:

1 From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 15, “System Configuration screen,” on page 47).

2 Select the system configuration and click **Show Audit Trail**. The System Audit Trail screen displays.

NOTE

Alternately, you can right-click the desired system configuration and select Show Audit Trail. The System Audit Trail screen displays as a result of either of these actions.

3 While holding the **Ctrl** key, select two or more versions and click **Differences** in the navigation bar. A change report displays. The report can be printed or exported.

NOTE

PCL6 or PPD printer drivers are required for printing a report.

Verify Integrity

To verify that the system configuration has not been changed outside of the 400-DS Workstation program, complete the following steps:

1 From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 15, “System Configuration screen,” on page 47).

2 Select the system configuration and click **Verify Integrity**. Either the data is verified successfully or the user is directed to contact their system administrator.

NOTE

Alternately, you can right-click the desired system configuration and select Verify Integrity. The integrity of the system configuration is checked as a result of either of these actions.

3 Click **OK** to close the Data Verification screen.

4 Close the System Configuration screen.

Import/Export XML File

To use an existing system configuration from one 400-DS Workstation computer on a different 400-DS Workstation computer, you can export and import the system configuration as an XML file.

To export the system configuration, complete the following steps:

1 From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 15, “System Configuration screen,” on page 47).

2 Select the desired system configuration.

3 Click **Export**. The Version Selection screen displays.

NOTE Alternately, you can right-click the desired system configuration and select Export. The Version Selection screen displays as a result of either of these actions.

4 If applicable, indicate which version to export and click **OK**. The Export System to XML File screen displays.

NOTE Each time a system configuration is saved, a new version is created. To export a version other than the most recently saved, indicate the appropriate version number on the Version Selection screen.

5 Indicate the directory and file name and click **Save**. The code is saved as an XML file.

To import the XML file at another 400-DS Workstation, complete the following steps:

1 From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 15, “System Configuration screen,” on page 47).

2 Click **Import**. The Import System from XML File screen displays.

NOTE Alternately, you can right-click the desired system configuration and select Import. The Import System from XML File screen displays as a result of either of these actions.

3 Select the appropriate directory and file name and click **Open**. The system configuration displays on the System Configuration screen.

4 Close the System Configuration screen.

400-DS System Calibration

Volume Calibration

1. Place the tubing from the Media A valve into a suitable container with deionized water.
2. From the navigation bar, click **Configuration**.
3. Select desired configuration.
4. Click **Calibration**. The System Calibration screen displays.
5. Enter the type of media used during the calibration procedure.
6. Enter the density of the media used at ambient temperature.

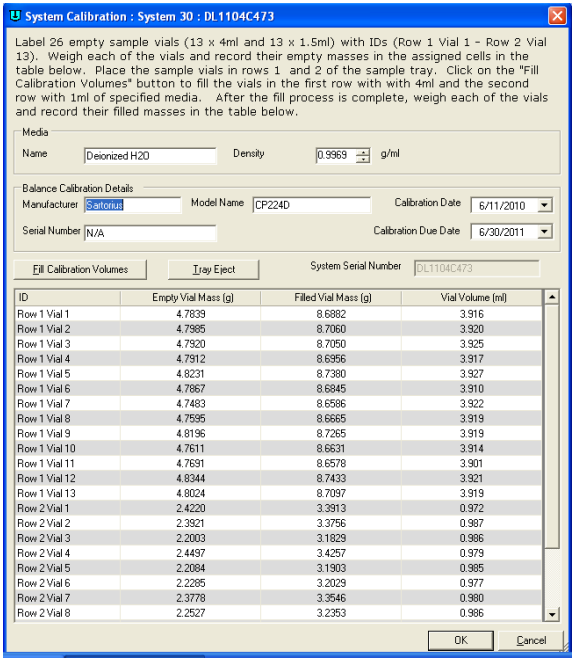

System Calibration : System 30 : DL1104C473
Label 26 empty sample vials (13 x 4ml and 13 x 1.5ml) with IDs (Row 1 Vial 1 - Row 2 Vial 13). Weigh each of the vials and record their empty masses in the assigned cells in the table below. Place the sample vials in rows 1 and 2 of the sample tray. Click on the "Fill Calibration Volumes" button to fill the vials in the first row with with 4ml and the second row with 1ml of specified media. After the fill process is complete, weigh each of the vials and record their filled masses in the table below.
Media
Name
Deionized H2O
Density
0.9969
g/ml
Balance Calibration Details
Manufacturer
Sartorius
Model Name
CP224D
Calibration Date
6/11/2010
Serial Number
N/A
Calibration Due Date
6/30/2011
Fill Calibration Volumes
Tray Eject
System Serial Number
DL1104C473
ID
Empty Vial Mass (g)
Filled Vial Mass (g)
Vial Volume (ml)
Row 1 Vial 1 4.7839 8.6882 3.916
Row 1 Vial 2 4.7985 8.7060 3.920
Row 1 Vial 3 4.7920 8.7050 3.925
Row 1 Vial 4 4.7912 8.6956 3.917
Row 1 Vial 5 4.8231 8.7380 3.927
Row 1 Vial 6 4.7867 8.6845 3.910
Row 1 Vial 7 4.7483 8.6586 3.922
Row 1 Vial 8 4.7595 8.6665 3.919
Row 1 Vial 9 4.8196 8.7265 3.919
Row 1 Vial 10 4.7611 8.6631 3.914
Row 1 Vial 11 4.7691 8.6578 3.901
Row 1 Vial 12 4.8344 8.7433 3.921
Row 1 Vial 13 4.8024 8.7097 3.919
Row 2 Vial 1 2.4220 3.3913 0.972
Row 2 Vial 2 2.3921 3.3756 0.987
Row 2 Vial 3 2.2003 3.1829 0.986
Row 2 Vial 4 2.4497 3.4257 0.979
Row 2 Vial 5 2.2084 3.1903 0.985
Row 2 Vial 6 2.2285 3.2029 0.977
Row 2 Vial 7 2.3778 3.3546 0.980
Row 2 Vial 8 2.2527 3.2353 0.986
OK
Cancel

Figure 18 System Calibration screen

7. Label 13 empty 4 mL sample vials (Row 1 Vial 1 - Row 1 Vial 13).

8 Label 13 empty 1.5 mL sample vials (Row 2 Vial 1 - Row 2 Vial 13).

9 Weigh each of the vials and record the empty masses in the assigned cells in the table.

10 Place the sample vials in row 1 (4 mL) and row 2 (1.5 mL) of the sample tray.

11 Click **Fill Calibration Volumes** to fill the vials in the first row with 4 mL and the second row with 1 mL of deionized water.

12 After the fill process is complete, weigh each of the vials and record their filled masses in the table. The vial volume calculates and displays in the table automatically.

13 Click **OK**. The Reason for Change screen displays.

NOTE

The software performs a Least Squares Fit analysis. The volume deviation from the curve is 1.5% of the vial volume. An automated error message is generated if the calibration fails.

14 Enter a reason code and change description and click **OK**.

15 Highlight the appropriate system.

16 Click **Properties**.

17 Click **Next** and ensure the Volume Calibration Coefficients are visible.

18 Click **Finish**.

19 Close the System Configuration screen.

Temperature Calibration

NOTE

If a previous temperature calibration has been performed, it is necessary to reset the cell temperature values before executing this procedure:

Step 1. Click Configuration.

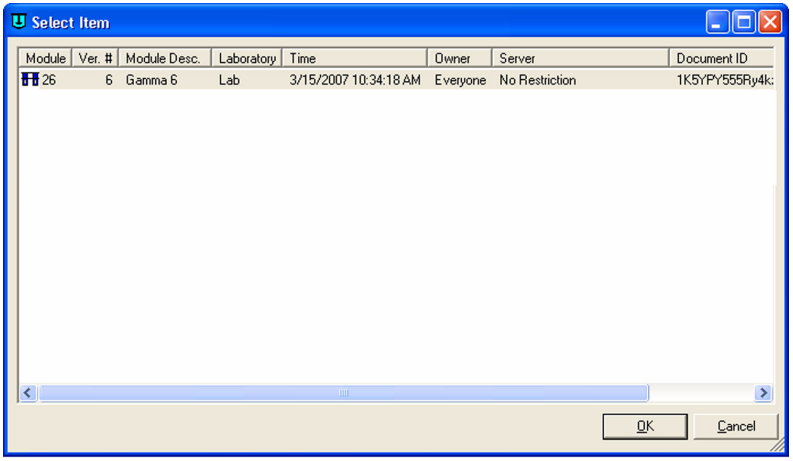
Step 2. Select the appropriate system from System Configuration.

Step 3. Click Next (from System Editor).

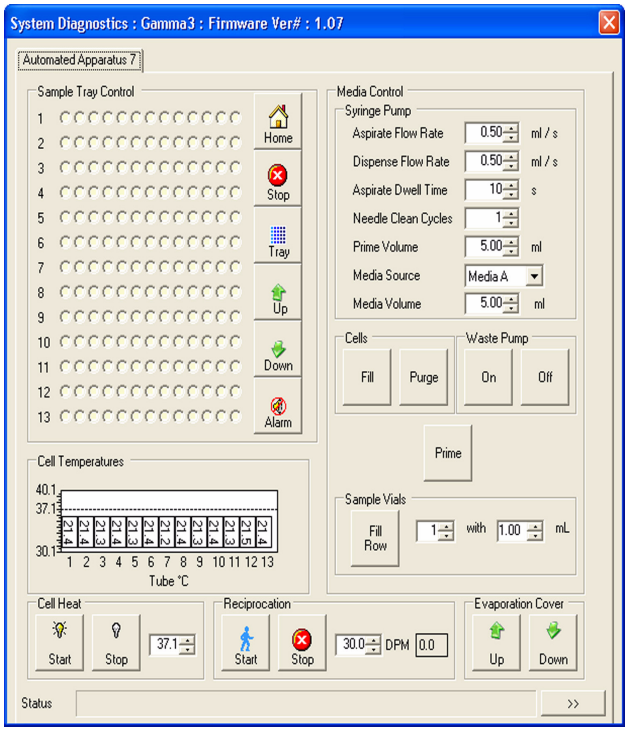
All channels should be set to the desired temperature (ºC).

---

1. Place the rinse media line into a suitable container holding deionized water.
2. Ensure sample holders are installed in each sample cell.
3. From the navigation bar, click **Diagnostics**. The Select Item screen displays.



4 Select the desired system and click **OK**. The System Diagnostics screen displays.



5 Ensure the media source option selected is Rinse Media. In the Cells box under Media Control, click **Fill**. Media moves into the cells.

6 In the Cell Heat box, set the cell temperature to the desired temperature.

7 Click Start (start heating). DO THE SAMPLE CELLS CONTAIN LIQUID? displays.

8 Click **Yes**. The temperatures display in the Cell Temperature box.

9 Set the reciprocation rate to at least 20 DPM and click Start.

10 Allow the media to equilibrate to the set temperature.

11 Fill a beaker with a sufficient amount of deionized water and verify the temperature using a calibrated thermometer. Record the value.

NOTE If using the standard QA Station probe, it will be necessary to first verify the temperature with the QA Station probe and then replace it with the Agilent 400-DS modified probe.

12 Using the modified temperature probe, confirm the temperature of the beaker of deionized water. Record the value. Temperatures should match ± 0.2 ºC.

13 In the Evaporation Cover box, click the **up arrow** to raise the evaporation cover.

14 Remove the two thumb screws from the evaporation cover and remove the evaporation cover.

15 Remove the sample holder for Cell 1 and replace it with the modified temperature probe.

16 Close the top cover of the Agilent 400-DS. Allow the temperature to stabilize and record the temperature.

17 Repeat steps 14 - 16 for each additional cell.

18 Reinstall the sample holders and the evaporation cover.

19 Close the Diagnostics screen.

20 From the navigation bar, click **Configuration**. The System Configuration screen displays.

21 Select the appropriate system and double-click to open. The System Editor screen displays.

22 Click **Next**. Enter the Setpoint temperature.

23 Enter the temperature values for each cell (as recorded in the table beneath Step 40) into the cell calibration field.

24 Click **Finish**. The Reason for Change screen displays.

25 Enter a reason code and change description and click **OK**.

26 Close the System Configuration screen.

NOTE To update the 400-DS Workstation Software with the new temperature values, initiate a new method. See “Creating a Method” on page 67 and “Running a Method” on page 80.

27 From the navigation bar, click **Diagnostics**. The Select Item screen displays.

28 Highlight the system being qualified and click **OK**.

29 In the Cell Heat box, set the cell temperature.

30 Click

(start heating). DO THE SAMPLE CELLS CONTAIN LIQUID? displays.

31 Click **Yes**. The temperatures display in the Cell Temperature box.

32 If necessary, set the reciprocation rate and click

.

33 Allow the media to equilibrate to the set temperature.

34 Record the temperatures displayed for each position.

35 Remove the two thumb screws from the evaporation cover and remove the cover.

36 Remove the sample holder for Cell 1 and replace it with the modified temperature probe.

37 Close the top cover of the Agilent 400-DS. Allow the temperature to stabilize.

38 After stabilization, record the temperature displayed on the QA Station.

39 Repeat steps 36 - 38 for each additional sample cell position.

NOTE

The temperatures displayed in the 400-DS Workstation Software should match the modified QA Station temperature probe ± 0.2 ºC to ensure accurate temperatures.

40 Replace the sample holders and the evaporation cover.

41 Click **Purge** to empty the sample cells.

42 Close the Diagnostics screen.

Manual Control/Diagnostics

To check the diagnostics of a dissolution apparatus, complete the procedures on the following pages. These procedures are performed on one system at a time. Repeat the procedures as applicable for each additional system.

1 From the navigation bar, click **Diagnostics**. The Select Item screen displays.

2 Select the desired system and click **OK**. The System Diagnostics screen displays.

Verifying Sample Tray Control

1 Click any vessel position corresponding to the desired row in the Sample Tray Control box. The tray moves and the indicated row raises.

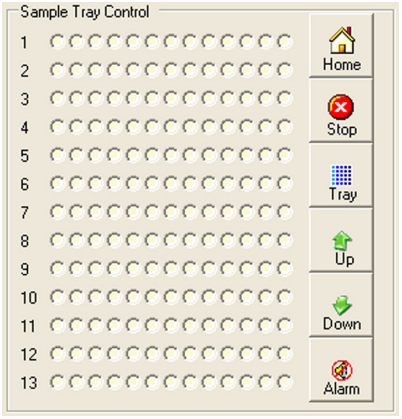


Figure 19 Sample Tray Control box

2 Click under the Sample Tray Control box. The drive unit returns to the home position.

3 Click to stop the movement.

4 Click to eject or retract the sample tray. Select **Ship** to place the tray in ship mode.

5 Click to raise the sample tray row.

6 Click to lower the sample tray row.

7 Click to turn off any audible alarm.

Verifying Media Control

1 Under the Media Control box, set the following parameters:

Table 4 Media Control Options

Option	Description
Aspirate Flow Rate (mL/s)	Use the up and down arrows to indicate the rate at which the media is pulled into the syringe.
Dispense Flow Rate (mL/s)	Use the up and down arrows to indicate the rate at which the media is dispensed from the syringe.
Aspirate Dwell Time (s)	Use the up and down arrows to indicate the duration of time the plunger holds at the top of the stroke before dispensing. **Note:** The time specified is for full syringe volume. For smaller syringe volumes, it is calculated proportionately.
Needle Clean Cycles	Use the up and down arrows to indicate the number of times the unit performs the needle cleaning cycle.
Prime Volume (mL)	Use the up and down arrows to indicate the volume to be pulled before taking measurement.
Media Source	Use the drop-down arrow to indicate the source of the media.
Media Volume	Use the up and down arrows to indicate the desired volume of the media.

2 Under the Media Control box, click **Prime**.

3 Under the Cells box, click **Fill**. The media moves into the cells.

CAUTION Do not click Fill more than one time without purging in between. The media will overflow the cells.

4 Under the Sample Vials box, use the up and down arrows to indicate the desired row number to sample into and the desired volume.

5 Ensure the selected row contains vials in all positions. Under the Sample Vials box, click **Fill Row**. The media moves from the cell into the sample vial.

6 Under the Waste Pump box, click **On** to turn on the waste pump.

7 Under the Waste Pump box, click **Off** to turn off the waste pump.

Verifying the Cell Temperature

1 In the Cell Heat box, use the up and down arrows to set the media cell temperature to an appropriate temperature (see the sample screen below).

2 Click

. DO THE SAMPLE CELLS CONTAIN LIQUID? displays.

CAUTION Do not begin heating the sample cells if they are empty as this can damage the heating jacket. Ensure the each cell is filled with media before activating the heater(s).

3 Click **Yes**. The temperatures display in the Cell Temperature box.

4 As applicable, click

.

5 Under the Cells box, click **Purge** to purge the remaining media from the tube.

Verifying Reciprocation

To set the dips per minute, complete the following steps:

1 In the Reciprocation box, use the up and down arrows in the box that corresponds to DPM, to set the dips per minute to a desired value and click

. Dipping begins.

Figure 20 Reciprocation box

2 Click

. The dipping stops.

Evaporation Cover Control

To raise the evaporation cover, click

in the Evaporation Cover box.

To lower the evaporation cover, click

in the Evaporation Cover box.

Method Editor

1 From the navigation bar, click **Editor**. The Methods screen displays. All test parameters are entered via the Method Editor screen.

Function	Procedure
Create a new method	See “Creating a Method” on page 67.
Copy a method	See “Copying Methods” on page 74.
Delete a method	See “Deleting Methods” on page 74.
Edit an existing method	See “Editing an Existing Method” on page 74.
Run a report of the method setup	See “Method Report” on page 75.
View the method audit trail	See “Show Audit Trail” on page 76.
Verify the integrity of a method	See “Verify Integrity” on page 77.
Import or export the method between two 400-DS Workstations	See “Import/Export XML File” on page 77.

Creating a Method

To create a new method, complete the following steps:

1 From the navigation bar, click **Editor**. The Methods screen displays.

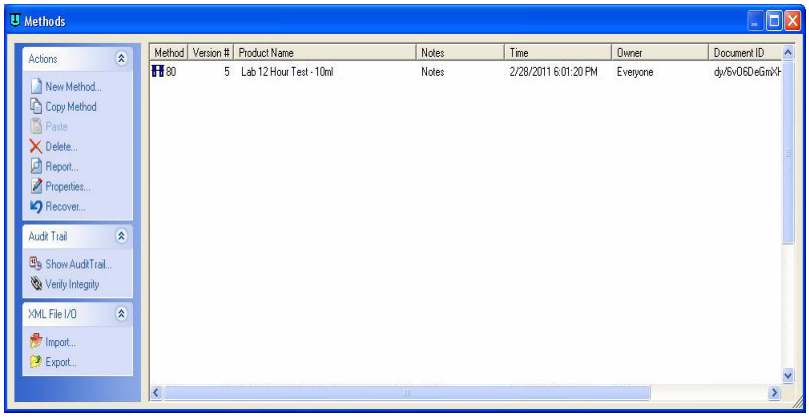


Figure 21 Methods screen

2 Click **New Method**. The Method Editor screen displays.

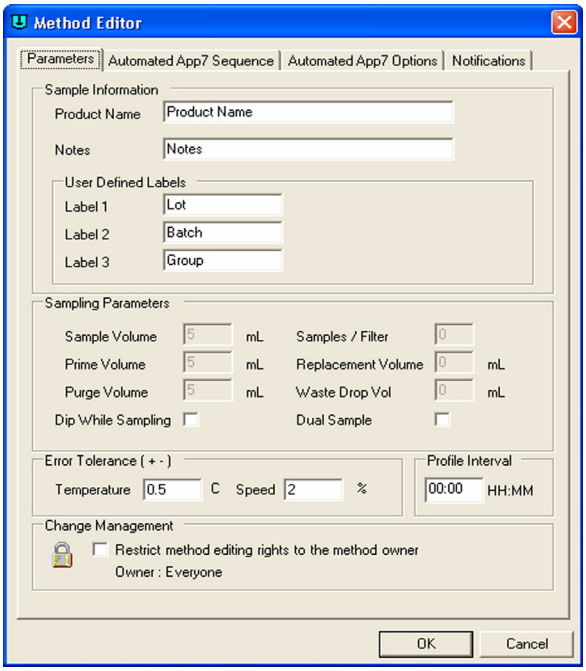


Figure 22 Method Editor screen

3 Select the **Parameters** tab.

Following is a description of the Parameters tab options:

Table 5 Parameters Tab Options

Option		Description
Sample Information	Product Name	Enter the name of the product.
	Notes	Enter any relevant notes regarding the sample.
	User Defined Labels Label 1 Label 2 Label 3	The fields in this area have default values of LOT, BATCH, and GROUP. These fields are customizable; enter the information that best serves the needs of the method parameters.
Error Tolerance (±)	Temperature	Enter the desired tolerance. If the tube temperature goes over or under the set temperature (see "Verifying the Cell Temperature" on page 64) by the amount of this tolerance, an error is recorded as part of the results.
	Speed	Enter the desired tolerance. If the RPM goes over or under the set speed (see "Verifying Reciprocation" on page 65) by the amount of this tolerance, an error is recorded as part of the results.
Profile Interval		Enter the timepoint in hh:mm format at which the temperature and speed settings are recorded. **Note:** Profile measurements are optional. Values are always recorded at sample timepoints independent of this setting.
Change Management		If applicable, select the box under Change Management in order to restrict the method editing rights to the current user or any user with VkModifyOthersMethod.

4 Select the **Automated App7 Sequence** tab (see Figure 23, "Automated App7 Sequence tab," on page 70).

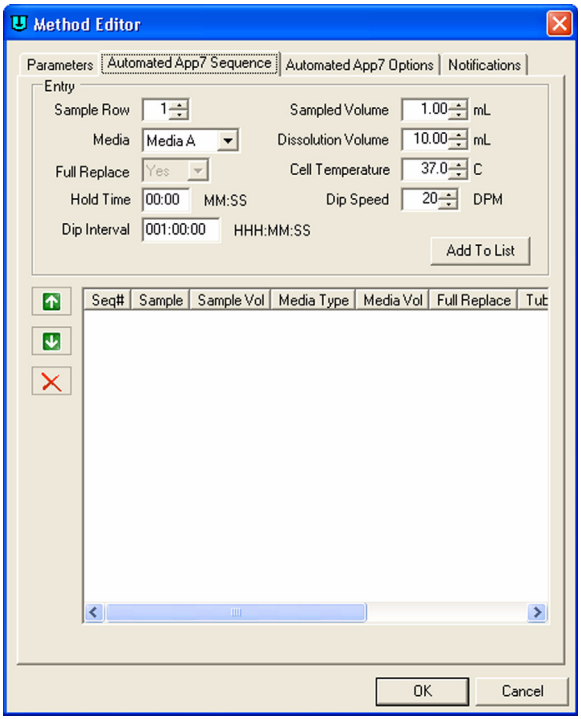


Figure 23 Automated App7 Sequence tab

Following is a description of the Automated App7 Sequence tab options:

Table 6 Automated App7 Sequence Options

Option	Description
Sample Row	Use the up and down arrows to indicate the sample tray row number for which the parameters are being set. After clicking **Add to List**, use the up and down arrows to indicate the next row. **Note:** The sample row will increment automatically from the previous timepoint.
Media	Use the drop-down arrows to indicate Media A, Media B, Media C, Media D, Media E, or Rinse media.
Sampled Volume (mL)	Use the up and down arrows to indicate appropriate volume based on your vial size.
Dissolution Volume (mL)	Use the up and down arrows to indicate appropriate volume based on the system cell size.
Cell Temperature	Enter the desired tube temperature in degrees Celsius for the first timepoint.
Hold Time (mm:ss)	Enter the desired duration for the sample holder to remain stationary prior to dipping in mm:ss format.
Dip Speed (DPM)	Use the up and down arrows to indicate the desired dips per minute (DPM) for each applicable row of the 400-DS.
Dip Interval (hhh:mm:ss)	Enter the desired duration for dipping in hhh:mm:ss format.

5 Select the **Automated App7 Options** tab.

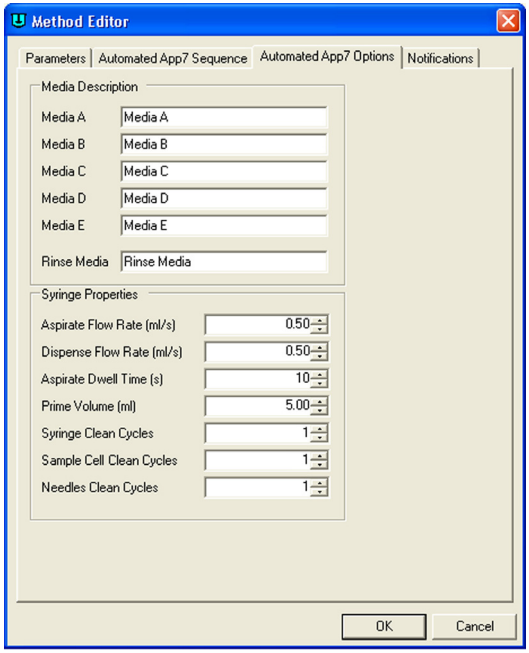


Figure 24 Automated App7 Options tab

Following is a description of the Automated App7 Options tab options:

Table 7 Automated App7 Options

Screen Section	Parameter	Description
Media Description	Media A Media B Media C Media D Media E Rinse Media	Enter descriptions as appropriate for the different medias.
Syringe Properties	Aspirate Flow Rate (mL/s)	Use the up and down arrows to indicate the rate at which the media is pulled into the syringe.
	Dispense Flow Rate (mL/s)	Use the up and down arrows to indicate the rate at which the media is dispensed from the syringe.
	Aspirate Dwell Time (s)	Use the up and down arrows to indicate the duration of time the plunger holds at the top of the stroke before dispensing. **Note:** The time specified is for full syringe volume. For smaller syringe volumes, it is calculated proportionately.
	Prime Volume (mL)	Use the up and down arrows to indicate the volume to be pulled before taking a sample.
	Syringe Clean Cycles	Use the up and down arrows to indicate the number of times to rinse the syringe between samples.
	Sample Cell Clean Cycles	Use the up and down arrows to indicate the number of times to rinse the sample cell between samples.
	Needles Clean Cycles	Use the up and down arrows to indicate the number of times to rinse the needles between samples

6 Select the **Notifications** tab.

7 Enter appropriate address(es) to receive notification of system operation (if applicable).

8 Indicate which options would require notification.

9 Click **OK** to close the Method Editor screen.

10 Close the Methods screen.

Copying Methods

To copy a method, complete the following steps:

1. From the navigation bar, click **Editor**. The Methods screen displays (see Figure 21, “Methods screen,” on page 67).
2. Select the desired method.
3. Click **Copy Method**.
4. Click **Paste**. A new method displays. The description of the new method is *Copy of...*.
5. To change any of the parameters of the method, see “Editing an Existing Method” on page 74.

Deleting Methods

To delete a method, complete the following steps:

1. From the navigation bar, click **Editor**. The Methods screen displays (see Figure 21, “Methods screen,” on page 67).
2. Select the desired method.
3. Click **Delete**.
4. Click **Yes**.

NOTE

A deleted method can be recovered at any time. See “Recovering a Method” on page 76.

Editing an Existing Method

To edit a method already entered on the 400-DS Workstation, complete the following steps:

1. From the navigation bar, click **Editor**. The Methods screen displays (see Figure 21, “Methods screen,” on page 67).
2. Click the desired method.

3 Click **Properties** on the navigation bar. The Method Editor screen displays (see Figure 22, “Method Editor screen,” on page 68).

NOTE

Alternately, you can double-click the desired method or right-click the desired method and select Properties. The Method Editor screen displays as a result of any of these actions.

4 Select the appropriate tabs and change the relevant information in the same manner that the method was created.

Method Report

To display a report of the method parameters, complete the following steps:

1 From the navigation bar, click **Editor**. The Methods screen displays (see Figure 21, “Methods screen,” on page 67).

2 Select the desired system configuration.

3 Click **Report**. The Version Selection screen displays.

4 If applicable, indicate which version and click **OK**.

NOTE

Each time a method is changed, a new version is created. To create a report of a version other than the most recently saved, indicate the appropriate version number on the Version Selection screen.

5 The method report displays. The report can be printed, exported, searched, verified, and/or signed.

Recovering a Method

To recover a method, complete the following steps:

1 From the navigation bar, click **Editor**. The Methods screen displays (see Figure 21, “Methods screen,” on page 67).

2 Click Recover. The Select Deleted Method(s) to Recover, screen displays.

3 Select the method to recover and click **OK**.

Method Audit Trail

Once a method has completed, the results are available for review, audited modification, and electronic signature. The software maintains complete history for all runs executed on the system. Results can be previewed and printed.

Show Audit Trail

To display the audit trail for a method, complete the following steps:

1 From the navigation bar, click **Editor**. The Methods screen displays (see Figure 21, “Methods screen,” on page 67).

2 Select the method and click **Show Audit Trail**. The Method Audit Trail screen displays.

NOTE

Alternately, you can right-click the desired method and select Show Audit Trail. The Method Audit Trail screen displays as a result of either of these actions.

3 While holding the **Ctrl** key, select two or more versions and click **Differences** in the navigation bar. A change report displays. The report can be printed or exported.

Verify Integrity

To verify that the method has not been changed outside of the application, complete the following steps:

1 From the navigation bar, click **Editor**. The Methods screen displays (see Figure 21, “Methods screen,” on page 67).

2 Select the method and click **Verify Integrity**. Either the data is verified successfully or the user is directed to contact their system administrator.

NOTE Alternately, you can right-click the desired method and select Verify Integrity. The integrity of the method is checked as a result of either of these actions.

Import/Export XML File

To use an existing method from one 400-DS Workstation on a different 400-DS Workstation, you can export and import the method as an XML file.

To export the method, complete the following steps:

1 From the navigation bar, click **Editor**. The Methods screen displays (see Figure 21, “Methods screen,” on page 67).

2 Select the desired method.

3 Click **Export**. The Version Selection screen displays.

NOTE Alternately, you can right-click the desired method and select Export. The Version Selection screen displays as a result of either of these actions.

4 If applicable, indicate which version to export and click **OK**. The Export Method to XML File screen displays.

NOTE Each time a method is saved, a new version is created. To export a version other than the most recently saved, indicate the appropriate version number on the Version Selection screen.

5 Indicate the directory and file name and click **Save**. The code is saved as an XML file which displays in Windows Notepad.

6 Close the file.

To import the XML file at another 400-DS Workstation, complete the following steps:

1 From the navigation bar, click **Editor**. The Methods screen displays (see Figure 21, “Methods screen,” on page 67).

2 Click **Import**. The Import Method from XML File screen displays.

NOTE

Alternately, you can right-click the desired method and select Import. The Import Method from XML File screen displays as a result of either of these actions.

3 Select the appropriate directory and file name and click **Open**. The method displays on the Method screen.

Active Channel Selection Valves

The Agilent 400-DS is equipped with channel selection valves which allow the you to isolate and shut off any unused sample cells. For example, if an experiment only required the use of eight sample vessels, Vessels 9 - 13 could be shut off by closing the red channel selection valves.

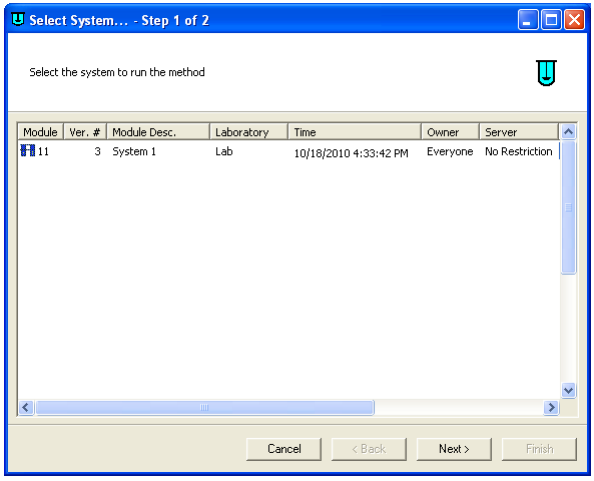
1. Identify the sample cells you want to disable and their corresponding valves.
2. Turn the red knob(s) clockwise one quarter turn.
3. To re-enable a valve, turn the applicable knob one quarter turn counterclockwise.
4. The number of active channels is programmed as part of the Method Start options just before the test begins.

CAUTION 400-DS sample cells are numbered left to right. To prevent damage to the heater jackets, close the valves from right to left when less than 13 active channels are used.

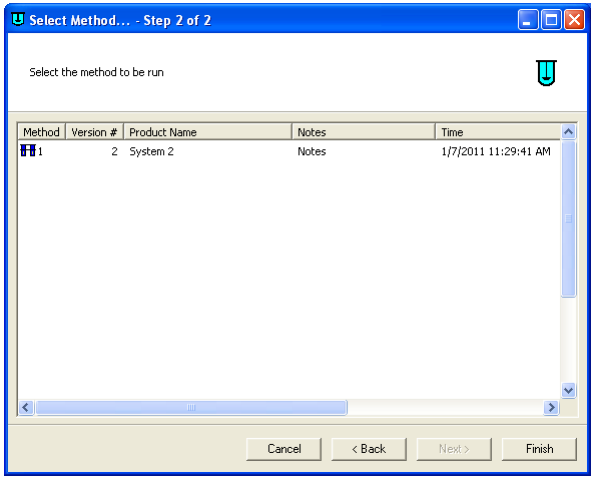
CAUTION Ensure sample vials are present in positions 1 and 13 of each sample tray row if less than 13 active channels are used. This provides proper sensing, alignment, and balance for each sample tray.

Running a Method

1 From the navigation bar, click **Run Method**. The Select System Step 1 of 2 screen displays.



2 Select the desired system to run the method and click **Next**. The Select Method Step 2 of 2 screen displays.



3 Select the desired method to run and click **Finish**. The system status screen displays.

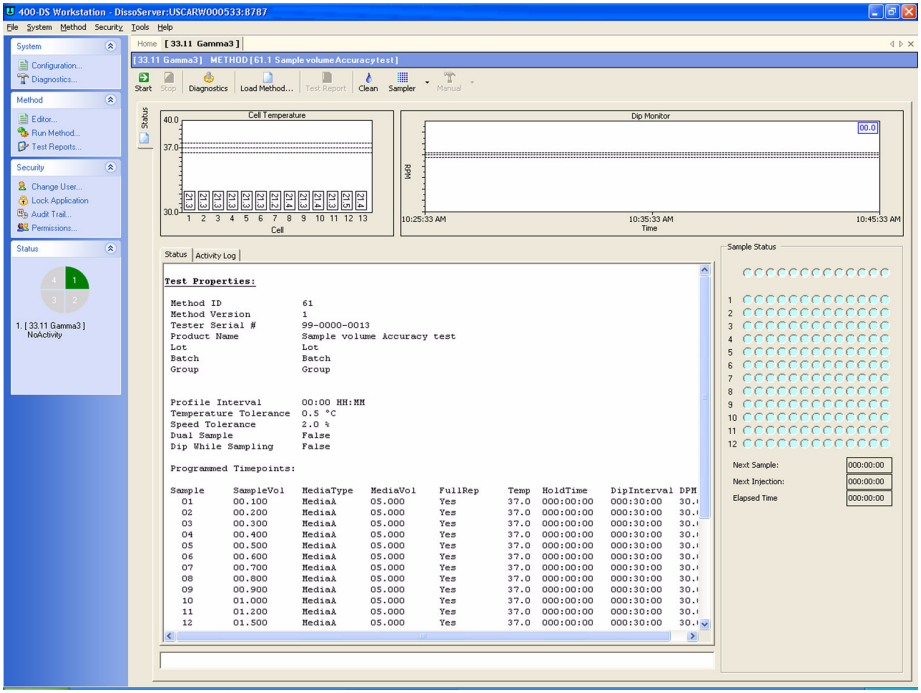

400-DS Workstation - DissoServer:USCARW000533:8787
File System Method Security Tools Help
Home [33.11 Gamma3]
[33.11 Gamma3] METHOD [61.1 Sample volume Accuracy test]
Start Stop Diagnostics Load Method... Test Report Clean Sampler Manual
Cell Temperature
Dip Monitor
Status
Activity Log
Test Properties:
Method ID 61
Method Version 1
Tester Serial # 99-0000-0013
Product Name Sample volume Accuracy test
Lot Lot
Batch Batch
Group Group
Profile Interval 00:00 HH:MM
Temperature Tolerance 0.5 °C
Speed Tolerance 2.0 %
Dual Sample False
Dip While Sampling False
Programmed Timepoints:
Sample SampleVol MediaType MediaVol FullRep Temp HoldTime DipInterval
01 00.100 MediaA 05.000 Yes 37.0 000:00:00 000:30:00
02 00.200 MediaA 05.000 Yes 37.0 000:00:00 000:30:00
03 00.300 MediaA 05.000 Yes 37.0 000:00:00 000:30:00
04 00.400 MediaA 05.000 Yes 37.0 000:00:00 000:30:00
05 00.500 MediaA 05.000 Yes 37.0 000:00:00 000:30:00
06 00.600 MediaA 05.000 Yes 37.0 000:00:00 000:30:00
07 00.700 MediaA 05.000 Yes 37.0 000:00:00 000:30:00
08 00.800 MediaA 05.000 Yes 37.0 000:00:00 000:30:00
09 00.900 MediaA 05.000 Yes 37.0 000:00:00 000:30:00
10 01.000 MediaA 05.000 Yes 37.0 000:00:00 000:30:00
11 01.200 MediaA 05.000 Yes 37.0 000:00:00 000:30:00
12 01.500 MediaA 05.000 Yes 37.0 000:00:00 000:30:00
Sample Status
Next Sample:
Next Injection:
Elapsed Time

Figure 25 System status screen

4 If necessary, remove the evaporation cover.

5 Place the samples on or in the sample holder.

6 Insert the sample holders into the sample cells.

7 Reinstall the evaporation cover and tighten the two thumb screws.

8 Place the capped sample vials in the applicable sample rows.

CAUTION Ensure sample vials are present in positions 1 and 13 of each sample tray row if less than 13 active channels are used. This provides proper sensing, alignment, and balance for each sample tray.

9 Click **Sampler** > **Load** to load the tray.

10 Fill applicable media containers.

11 Click **Start**. The Method Start Options screen displays (see Figure 26, “Method Start Options screen,” on page 82).

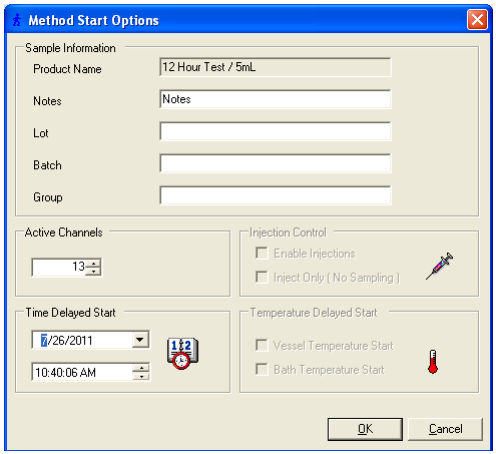


Figure 26 Method Start Options screen

Following is a description of the Method Start Options screen options:

Table 8 Method Start Options

Screen Section	Parameter	Description
Sample Information	Product Name	Enter the product name.
	Notes	Enter any appropriate notation.
	Label 1	Enter the appropriate information based on the user-defined labels (see “User Defined Labels” on page 69).
	Label 2	
	Label 3	
Active Channels	Enter the number of active heating channels. **Note:** Heating channels are counted from left to right. See “Active Channel Selection Valves” on page 79	
Injection Control	Enable Injections	N/A

Table 8 Method Start Options

Screen Section	Parameter	Description
Temperature Delayed Start	Vessel Temperature Start	N/A
	Bath Temperature Start	N/A
Time Delayed Start	Use this option to program a delayed start. Enter the desired date and time to start the method.	

12 Click **OK**. The Method Sample Information screen displays.

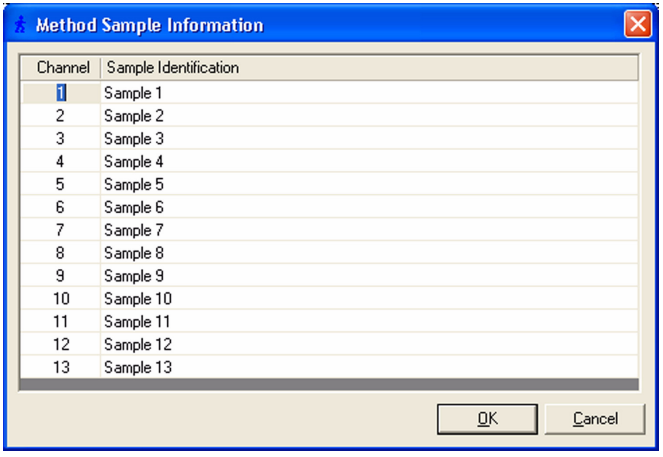


Figure 27 Method Sample Information Screen

13 Enter the sample information, if applicable.

NOTE

If the method requires more than 12 sample rows, complete the following steps:

1. Upon completion of filling the 12th sample row, click **Sampler** > **Eject Tray**.
2. Replace the sample rows with the required amount of fresh sample vials.
3. Load the new sample tray.
4. Click **Sampler** > **Load New Tray**.

NOTE

Vials may be removed or replaced at any time after a sample row has been completed, provided a sample is not occurring.

14 When the method is complete, click **Test Report**. The test report displays. The report can be printed, exported, searched, verified, and/or signed.

Test Reports

To display a report of the completed method, complete the following steps:

1 From the navigation bar, click **Test Reports**. The Test Report Selection screen displays.

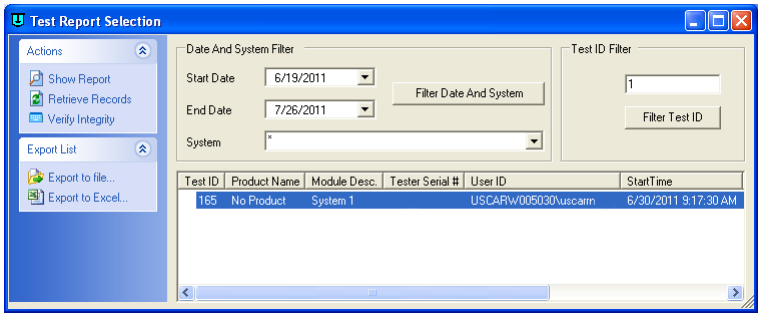


Figure 28 Test Report Selection screen

NOTE

By default, the test report dialog only shows tests done in the previous week. To view tests completed earlier than the previous week, click the **Start Date** and/or **End Date** drop-down arrows to indicate date range for a test report selection and click **Filter Date and System**.

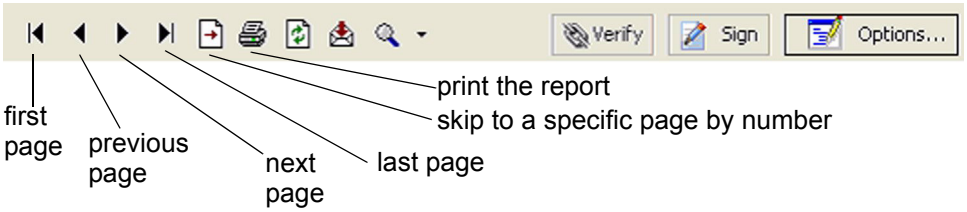
Additionally, you can select a system name from the **System** combo box to restrict the selection to a particular system.

To restrict the selection to a particular test identification, enter the value in the **Test ID Filter** box and click **Filter Test ID**.

2 Click a test in the list to select it.

3 From the navigation bar in the **Test Report Selection** dialog, click **Show Report**. The report for the selected test displays.

4 Using the buttons on the report toolbar, you can do the following:



Electronic Signatures

When the user is satisfied with the results, the results can be electronically signed. The software allows multiple electronic signings of a set of results. Each signing is accomplished using the signature dialog box shown. The user authenticity is determined by testing the user identification and password against the Windows security database.

Electronic signatures are permanently linked to the results. The software always requires the signature to be executed using all the signature components. Any attempts to sign a set of results using an invalid user identification, password, or any combination thereof that is incorrect is automatically recorded to the system audit trail.

Clean System

From the system status screen, click Clean. All instruments initialize. Media is pulled from the Rinse Media Container and cells are filled and expelled through the valves. The cells are aspirated and purged.

NOTE The 400-DS should be flushed / cleaned as soon as possible after a test. Multiple clean cycles may be necessary to properly rinse the system.

5
Troubleshooting and Maintenance

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Periodic Maintenance

WARNING **The 400-DS contains electrical circuits, devices, and components operating at dangerous voltages. Contact with these circuits, devices, and components can cause death, serious injury, or painful electric shock.**

Periodic maintenance needs may vary depending on frequency of instrument usage.

Calibration

Agilent recommends the 400-DS be calibrated at six-month intervals. However, based on your own SOPs, this can be extended for up to a year. Contact the Agilent Service Department to schedule periodic maintenance and qualification. The Agilent Service Department can be reached at 1.800.227.9770.

Routine Maintenance (to be Performed Between Each Dissolution Method

- Execute the Clean System cycle using the 400-DS Workstation software (“Clean System” on page 86). Ensure an appropriate cleaning solution is in place to thoroughly rinse the media lines and sample cells.

Sample Holders

- Clean sample holders thoroughly after each use and place them in an ultrasonic bath for a few minutes, if necessary.
- When using corrosive materials such as hydrochloric acid, surfactants, or medium containing salts, be sure to rinse the holders with deionized water immediately after use. Dry completely with a soft towel or cloth (preferably lint-free).
- Do not clean the sample holders with abrasive cleansers or cloths. Use deionized water whenever possible. If you must use cleanser or solvent, be sure that it is as mild as possible, non-abrasive, and fully compatible with fluorocarbons and stainless steel before use.
- It is suggested that the sample holders are cleaned by hand. Use of a laboratory dishwasher is NOT recommended.
- Handle with care at all times.
- Store the sample holders properly between each use.

Troubleshooting

The Agilent Service Department can assist you if you experience problems or questions concerning your 400-DS. Many problems can be traced to simple sources and are easily solved.

The Agilent Service Department can be reached at 1.800.227.9770.

6
Service and Warranty

Service and Warranty Information 92

The warranty is provided by Agilent Technologies, Inc. or one of its authorized representatives.

Service and Warranty Information

Agilent dissolution products carry a one-year warranty on parts and labor. The Dissolution Systems Service Department (or one of its representatives) will, at its option, either repair or replace any mechanical and electrical components in your instrument which prove to be defective. During the first year of warranty coverage, there is no charge for the labor to repair your unit. The Dissolution Systems Service Department (or one of its representatives) will determine the best site to repair the unit, either onsite or returned to Agilent Technologies, Inc. Any onsite warranty services are provided only at the initial installation point. Installation and onsite warranty services are available only in Dissolution Systems service travel areas.

Exclusions and Limitations

Excluded from this warranty are expendable or consumable items such as, but not limited to, paddles, baskets, vessels, and acrylic water baths. Also excluded are defects from improper or inadequate maintenance by the customer, user-induced chemical action or contamination, unauthorized modification or misuse, and improper site preparation and maintenance.

Operation of software is not warranted to be uninterrupted or error-free.

Obtaining Warranty Service

To obtain warranty service in the United States, contact the Dissolution Systems Service Department at 1.800.227.9770 to obtain authorization to return units for repair. At the option of the customer, onsite warranty service is available, but travel charges may be incurred. The customer should prepay all shipping charges for products returned to the Dissolution Systems Service Department (unless otherwise authorized), and Agilent Technologies, Inc. will pay all charges for return to the customer.

Warranty Limitations

Agilent Technologies, Inc. makes no other warranty, either express or implied, with respect to this product. Specifically disclaimed are any implied warranties of merchantability and fitness for a particular use. In no event will Agilent Technologies, Inc. be liable for any indirect, incidental, or consequential damages arising from the use of this product. This warranty gives you specific legal rights which may vary from state to state or province to province, so you may have other rights and some of these exclusions may not apply to you.

Exclusive Remedies

The remedies provided herein are the customer's sole and exclusive remedies. In no event shall Agilent Technologies, Inc. or its representatives be liable for any direct, indirect, special, incidental, or consequential damages, whether based on contract, tort, or any other legal theory. Some states or provinces do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

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